REMARKS/ARGUMENTS

Applicant would like to thank the Examiner for conducting an interview at the U.S. Patent and Trademark Office on Wednesday, June 6, 2007. According to the interview summary, an agreement with respect to the claims was reached and the Examiner would consider the response to the 112 issues that were raised in the Office Action. Therefore, the currently pending claims should be deemed allowable.

Claims 151-153, 156, 160-161, 167-170 and 174-210 are currently pending and stand rejected. By way of this response, four (4) claims have been amended, zero (0) independent claims have been added, zero (0) dependent claims have been added and two (2) claims have been cancelled. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

Support for amended claim 151, 152, 156 and 159 can be found in the specification and claims as originally filed at least at page 20, line 20 – page 21, line 10; page 22, line 11; page 25, lines 15-20; page 39, lines 12-14; page 44, lines 5-10; page 44, line 18 – page 145, line 6; page 159, line 19; and the Examples.

I. THE WRITTEN DESCRIPTION REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully requests that this rejection be withdrawn in light of the current amendments, made without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph and solely to expedite the prosecution of the present application.

II. THE ENABLEMENT REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

In view of the present amendments, Applicant submits that this rejection is moot. Examples XV and XVI, at pages 91-110 of the specification, clearly describe and enable the claimed invention. One skilled in the art would be able to modify the teachings of the ranges in the disclosure to make and use the claimed invention. Claim 151 requires buffering agent in an amount of about 0.2 mEq to 5 mEq per 2 mg of omeprazole. The term "milliequivalents" or

"mEq" inherently relates to the acid neutralizing capacity of a buffering agent and, therefore, the skilled artisan would certainly understand how to practice this element of the invention without undue experimentation.

Further, pharmacokinetic limitations such as "average plasma concentration of the omeprazole of at least about 0.1 μg/ml at any time within about 30 minutes after administration," are functional limitations, which are understood in the art and are permissible under applicable precedent. For example, in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 68 U.S.P.Q.2d 1865, 1873 (Fed. Cir. 2003), the Federal Circuit stated, "a functional limitation covers all embodiments performing the recited function." Here, although various buffering agents may differ by solubility (and hence rate of acid neutralization), the functional pharmacokinetic language limits the claim to those buffering agents (or mixtures thereof) that provide the claimed result and fall within the range of about 0.2 mEq to 5.0 mEq per 2 mg of omeprazole. *See also In re Swinehart*, 169 U.S.P.Q. 226 (C.C.P.A. 1971).

In response to the Office Action's contention that, "the result from administering the composition in fasting subject would not be supportive of the claims which does not require any limitation of the subject," Applicant submits that one skilled in the art would be able to determine plasma concentration and dosage relationship in different subjects, based on, for example, the embodiments of the disclosure, the pharmacological properties and activity of omeprazole and the individual subject being treated. By way of illustration and not limitation, Applicant submits that one of ordinary skill would be able to practice the claimed invention for a subject given the level of knowledge in the art and based upon page 20 lines 13-15, page 29 line 7 to page 30 line 10, page 30 line 17 to page 31 line 7, page 142 lines 14-17, the "Veterinary Formulations" set forth on pages 138-144 and the Claims in the specification as originally filed. *See In re Bundy*, 642 F.2d 430, 434, 209 U.S.P.Q. 48, 51-52 (C.C.P.A. 1981).

In light of the current amendments to the claims and the foregoing arguments, Applicant respectfully requests withdrawal of this rejection.

III. THE REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

The Final Office Action dated June 14, 2007 maintained the rejection of the claims under 35 U.S.C. § 102(b) as being anticipated by Carroll et al. ("Carroll"), U.S. Patent No. 5,447,918 ("McCullough"), WO 97/25066 ("Depui"), JP 05-255088 ("JP '088" or "Oishi") supplemented with Horowitz. Applicant respectfully traverses this rejection and hereby incorporates by

reference in entirety the arguments advanced in its response dated March 9, 2007. Moreover, none of these references disclose a storage stable powder for suspension with a thickening agent.

In light of the current amendments to the claims and the foregoing arguments, Applicant submits that no *prima facie* case of anticipation has been established and respectfully requests withdrawal of this rejection.

IV. REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

The Final Office Action dated June 14, 2007, maintained the rejection under 35 U.S.C. § 103(a) over Carroll et al. ("Carroll"), U.S. Patent No. 5,447,918 ("McCullough"), WO 97/25066 ("Depui"), JP 05-255088 ("JP '088" or "Oishi") in view of Carroll, U.S. Patent No. 5,443,826 ("Borody") and Horowitz.

Applicant hereby incorporates by reference in entirety the arguments advanced in its response dated March 9, 2007. Furthermore, Applicant submits that the combination of references does not teach or suggest the current claims. Borody is directed to administering a pharmaceutical composition comprising "a composition of fresh homologous faeces, equivalent freeze-dried and reconstituted faeces or a 'synthetic' faecal composition." Col. 4, ln 21-24. The composition may further contain omeprazole. Col. 4, ln 59-64. However, Borody fails to provide any teaching or suggestion of also employing a buffering agent—let alone about 5 mg to about 100 mg omeprazole plus about 0.2 mEq to 5 mEq buffering agent per 2 mg of omeprazole in an immediate release powder for suspension to provide the claimed plasma concentration. Furthermore, Borody does not teach or suggest this combination of components with a thickening agent.

For the foregoing reasons, Applicant submits that no *prima facie* case of obviousness has been established and respectfully requests withdrawal of this rejection.

V. OBVIOUSNESS-TYPE DOUBLE PATENTING

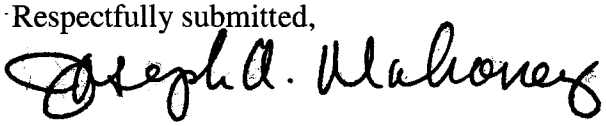
The claims stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the issued claims of U.S. 6,699,885; 6,645,988; 6,489,346; and 5,840,737 as described in the Office Action. Applicant will submit a terminal disclaimer upon the indication of allowable subject matter.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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